DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Denver District Office
Building 20 – Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

m3809r

January 24, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Mr. Mike McCloskey
Former Owner
Countyline Dairy #2
12392 Driftwood Drive
Demott, IN 46310

PURGED

Ref. #. – DEN-00-09

Dear Mr. McCloskey,

It is our information that your dairy operations have ceased at Countyline Dairy #2, 160 East Jackson Road, Lake Arthur, NM. Our investigation conducted by Food and Drug Investigator Margaret M. Annes on November 30 & December 2, 1999, was thus limited to obtaining a treatment print-out regarding the violative cow, which is described below, from Keith A. Vanderdusseu, your new partner at Countyline Dairy L.L.C. We also obtained documentation from [redacted]

When you owned and operated Countyline Dairy #2, you sold a cow on March 16, 1999 to [redacted] which was subsequently slaughtered for food and found to contain illegal levels of drug residues by USDA testing. The fact that you offered an animal for sale for slaughter as food, is a violation of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). This incident was recorded under USDA case # 99-0263-NM:

> **March 16, 1999** USDA analysis of tissue samples collected from your animal (USDA Sample #327421) identified the presence of Penicillin residues of [redacted] ppm in the kidney and [redacted] ppm in the liver. A tolerance of [redacted] has been established for residues of Penicillin in the edible tissues of cattle in Title 21 Code of Federal Regulations, Part 556.510 (21 CFR 556.510). USDA analysis also identified the presence of Sulfadimethoxine residues of [redacted] ppm in the liver and [redacted] ppm in the muscle. A tolerance of 0.1 has been established for Sulfadimethoxine residues in the edible tissues of cattle (21 CFR 556.640).

The violative cow was treated for a displaced abomasum while under your care and ownership. Your treatment record indicated she was not medicated, however this is highly unlikely for this condition. The presence of Sulfadimethoxine and Penicillin drugs at the levels found in edible tissues from this animal cause the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you held animals under conditions which were so inadequate that diseased and/or medicated animals bearing potentially harmful drug residues may enter the food supply. For example, you lacked an adequate system for assuring that animals medicated by you or under your direction have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues from edible tissues. The food from animals held under such conditions is adulterated within the meaning of section 402(a)(4) of the Act.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

The above is not intended as an all-inclusive list of violations. As a dairy farm operator and owner/seller of medicated animals for food use, you are responsible for assuring that your overall operation and the products you distribute are in compliance with the law. You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure and/or injunction.

This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies. To avoid future illegal residue violations you should take precautions such as:

1) Implement a system to withhold a medicated animal from slaughter for food for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal, then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.

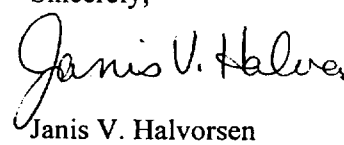
2) Implement a system for medical treatment records that include: drug used, treatment period, who administered the drug, amount administered, appropriate withdrawal period and the animal's identification.

You should notify this office in writing within 15 working days of the receipt of this letter, of the steps you will take to prevent similar deviations in other dairy operations in which you participate. Your response should include an explanation of each step being taken to prevent any violations at any dairy operations you now operate.

If corrective action cannot be completed within 30 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Betty Kay Baxter, Acting Compliance Officer, at the above address. If you have questions regarding this letter you may contact Ms. Baxter at (303) 236-3084.

Sincerely,



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Janis V. Halvorsen
Acting District Director